Application Number: 10/602,456
Balschmidt et al.
Filed: June 23, 2003
Attorney Docket No.: 6460.200-US
Via Facsimile No.: 571-273-8300

REMARKS

The examiner states in the Office Action Summary that claims numbered 1, 3-11 and 13-23 are pending in the application, and claims numbered 1, 3-11 and 13-23 are rejected.

The specification is amended herein. Claims numbered 1 and 6-11 are amended herein. Following entry if this amendment, claims numbered 1, 3-11, and 13-23 are pending in the present application.

Specification/Claims Objections

(1) The examiner has objected to the specification stating the terms "B28", "B32" and "A21" need to be clarified.

Applicant has amended the specification to include the requested clarifying language.

Applicant respectfully requests reconsideration and withdrawal of the objection to the specification.

Claim Rejections – 35 U.S.C. § 112, second paragraph

(2) The examiner has rejected claims numbered 1, 3-11 and 13-23 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularily point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 1 recites "a derivative of an analogue." The specification does not define the derivative of the peptide analogue. Note that on page 2, lines 22-24, the specification has defined the derivative as an analogue of the parent peptide; and thus, said recitation "derivative (analogue) of ... analogue" is awkward and indefinite.

Applicant respectfully disagrees with the examiner's assertion that the specification has defined the derivative as an analogue of the parent peptide. Page 2, lines 22-24 states: "The term "derivative' as used herein designates a **peptide** in which *one or more of the amino acid residues* **of** the *parent peptide* **or** *analogue of the parent peptide* **have been chemically modified**, eg by alkylation, acylation, ester formation or amide formation." (emphasis added). However, to advance prosecution Applicant has amended claim number 1 to include clarifying language.

Applicant respectfully requests reconsideration and withdrawal of this rejection.

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Claim Rejections – 35 U.S.C. § 103

(3) The examiner has rejected claims numbered 1 and 3-11 under 35 U.S.C. § 103 (a) as being unpatentable over Marini, J.L. (U.S. 6,328,987) when taken withHerschler, R.J. (U.S. 4,973,605). The examiner states Marini teaches, in the patent claims 1-3, a composition comprising human alpha interferon-2 and methylsulfonylmethane (dimethyl sulfone), but Marini does not teach the concentration of dimethyl sulfone administered. The examiner further states Herschler teaches a suitable dimethyl sulfone concentration is about 5.5 to 10.9 mg/mL.

Applicant has amended claim 1 to further clarify the the subject matter of the claimed invention.

Applicant respectfully requests reconsideration and withdrawal of the rejection of claims numbered 1 and 3-11 under 35 U.S.C. § 103 (a).

(4) The examiner has rejected claims numbered 1, 3-11 and 13-14 under 35 U.S.C. § 103 (a) as being unpatentable over Pierce, S.W. (U.S. 6,924,273 taken with Herschler, R.J. (U.S. 4,973,605). The examiner states Pierce teaches a composition comprising insulin and dimethyl sulfone, the solution is an aqueous solution or suspension, and various routess of administration, but Pierce does not expressly teach the concentration of dimethyl sulfone administered. The examiner further states Herschler teaches a suitable dimethyl sulfone concentration is about 5.5 to 10.9 mg/mL.

Applicant has amended claim 1 to further clarify the the subject matter of the claimed invention.

Applicant respectfully requests reconsideration and withdrawal of the rejection of claims numbered 1, 3-11, and 13-14 under 35 U.S.C. § 103 (a).

To further prosecution of the present application, Applicant has amended claim 1 to include additional limitations and respectfully submits the amendment obviates the examiner's rejection. However, Applicant respectfully disagrees with the examiner's assertion that the present claims are rendered obvious by the cited references. Applicant respectfully submits the

Herschler reference (U.S. 4,973,605), the Marini reference (U.S. 6,328,987), and the Pierce reference (U.S. 6,924,273) cited by the examiner are not references that are either in the field of the Applicants endeavor or reasonably pertinent to the specific problem with which the Applicant was involved. The Federal Circuit has stated that [a] reference is reasonably pertinent if ... it is one which, because of the matter with which it deals, logically would have commended itself to the inventor's attention in considering his problem....If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem....[I]f it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it. *In re Clay*, 966 F.2d 656 (Fed. Cir. 1992). Applicant respectfully asserts enhancing tissue penetration of physiologically active agents with DMSO, the use of MSM to relieve pain and nocturnal cramps and to reduce stress-induced deaths in animals, cosmetic topical preparations, and orally administratable chondroprotective/restorative compositions have little relevance to the use of MSM as an isotonicity agent for pharmaceutical compositions for parenteral administration. Applicant respectfully notes motivation to combine these diverse references to arrive at Applicant's claimed invention is not apparent.

Additionally, it appears the examiner has included separate references to represent the different features described in the claims of the instant application. The examiner has pieced together the claimed invention using Applicant's claimed invention as a guide. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teaching of the prior art so that the claimed invention is rendered obvious. One cannot use hindsight reconstruction to pick and choose among disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 823 F.2d 1071 (Fed. Cir. 1988). Applicant respectfully requests the examiner consider the claim as a whole.

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The examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this response or application.

Respectfully submitted,

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